

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
<p>The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Service Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.</p> <p><b>PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ORGANIZATION.</b></p>					
1. REPORT DATE (DD-MM-YYYY) 10/15/2017		2. REPORT TYPE Presentation		3. DATES COVERED (From - To) 10/15/2017-10/18/2017	
4. TITLE AND SUBTITLE Saline Alone vs Saline plus Mannitol Hydration for the Prevention of Acute Cisplatin Nephrotoxicity: A Randomized Trial				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Lt Col Wilfred Delacruz				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 59th Clinical Research Division 1100 Willford Hall Loop, Bldg 4430 JB SA-Lackland, TX 78236-9908 210-292-7141				8. PERFORMING ORGANIZATION REPORT NUMBER  17374	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) 59th Clinical Research Division 1100 Willford Hall Loop, Bldg 4430 JB SA-Lackland, TX 78236-9908 210-292-7141				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release. Distribution is unlimited.					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Clarice Longoria
					19b. TELEPHONE NUMBER (Include area code) 210-292-7141

## **Saline Alone vs Saline plus Mannitol Hydration for the Prevention of Acute Cisplatin Nephrotoxicity: A Randomized Trial**

Wilfred Dela Cruz, Frederick Flynt, Sandra Terrazzino, Naomi Hullinger, Melissa King, James Aden, Doug Nelson, Tiffany Byrd  
San Antonio Military Medical Center, San Antonio, TX/United States of America

### **Background**

Cisplatin is widely used as an effective chemotherapy in diverse neoplasms and is associated with renal toxicity. Several studies suggest that pre-hydration plus mannitol prior to chemotherapy with cisplatin prevents nephrotoxicity. The aim of this study is to determine the acute effects of hydration plus mannitol on renal function in patients receiving cisplatin.

### **Method**

Fifty patients who were eligible to receive chemotherapy with cisplatin alone or in combination with other chemotherapy were randomized to receive 1L saline alone (A) or saline plus mannitol before and after chemotherapy. The mannitol group received 12.5 g of mannitol in saline solution. Serum Creatinine (Ser Cr), BUN, and GFR were measured at baseline (no more than 3 days prior to therapy) and on Day 1, 5, and 14. Baseline characteristics were analyzed using t-tests or chi-squared tests. Repeated Measures (RM) ANOVA was used to compare the change in BUN, creatinine, GFR, and BUN to Creatinine ratio.

### **Result**

Data for 48 patients (36 male and 12 female) were collected. The median age is 57 (range 18 to 78); 23 received saline alone and 25 received mannitol. There are no difference between randomized groups between Age, Gender, and Race. The mean BUN and BUN to creatinine ratio significantly increased by 46% and 37% respectively ( $p < 0.001$ ), while the corresponding mean Serum Cr did not significantly change over time and mean GFR peaked at day 1 then decreased by day 5 ( $p = 0.001$ ). All variables returned to baseline by Day 15. Twenty patients (42%) had grade 1 increase in Ser Cr (25% in A and 17% in B,  $p = 0.078$ ). No patients had grade 2 or greater in the mannitol group, while 2 patients had grade 2 or grade 3 in saline only group. RM ANOVA analysis show no difference between randomized groups from baseline through Day 1, Day 5, and Day 14 for BUN, creatinine, GFR, and BUN to Creatinine ratio.

## **Conclusion**

Cisplatin caused acute decline in renal function as determined by BUN, BUN to Ser Cr ratio and GFR, however, addition of mannitol to pre-hydration fluid did not change the outcome.

Disclaimer: The views expressed are those of the authors and do not reflect the official view or policy of the Department of Defense or its components. The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02\_AFI 40\_402.